DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Donald J. Quigg
Acting Commissioner of
Patents and Trademarks
Washington, D.C. 20231

MAR 18 1985

Dear Commissioner Quigg:

This is in regard to the application for patent extension for U.S. Patent No. 4,217,347, filed by E.R. Squibb & Sons, Inc., under Title II of Public Law 98-417, 35 U.S.C. 156 et seq. The human drug product claimed by the patent is Capozide tablets (captopril and hydrochlorothiazide), New Drug Application (NDA) 18-709.

A review of the Food and Drug Administration's official records indicates that NDA 18-709 does not represent the first permitted commercial marketing or use of the active ingredients, captopril and hydrochlorothiazide. Our records indicate that these active ingredients were previously approved for marketing as follows: Capoten tablets (captopril, 25 mg, NDA 18-343) was approved on April 6, 1981, and hydrochlorothiazide is a drug that is the subject of several new drug applications that were first approved prior to 1962.

As required by 35 U.S.C. 156(d)(2)(A), we will determine the applicable regulatory review period, publish that determination in the FEDERAL REGISTER, and notify you of our determination. Should you conclude, on the basis of the above information, that the subject patent is ineligible for patent extension and a determination of the applicable regulatory review period is thus unnecessary, please advise us accordingly. Publication in the FEDERAL REGISTER is not expected within the next 10 days.

Please let me know if we can be of further assistance.

Sincerely,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs